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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,507	11/28/2001	Laixin Wang	3302.2.1	3067

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EXAMINER	
SCHNIZER, RICHARD A	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 01/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/996,507	WANG, LAIXIN	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D	1635	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 December 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *20 December 2004*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3.☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: *1-64*.

Claim(s) withdrawn from consideration: *65-83*.

8.☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____

Continuation of 3. Applicant's reply has overcome the following rejection(s): Applicant's reply overcomes the objections to claims 17, 30, 48, and 56..

Continuation of 5. does NOT place the application in condition for allowance because: The claims are drawn to compositions comprising a "biocompatible hydrophilic backbone polymer." The central issue is the definition of the term "backbone", and what is a reasonable interpretation of this term. Applicant argues at pages 20-29 of the response that Schacht does not teach a hydrophilic backbone polymer.

At page 20 of the response, Applicant argues that the polycationic polymer of Schacht, rather than the hydrophilic polymer, serves as a backbone. Applicant relies on Fig. 3 of Schacht which shows that more than one hydrophilic polymer may be attached to a single polycation. This is unpersuasive because Fig. 1 of Schacht clearly shows that the opposite is also true, i.e. multiple polycationic polymers may be linked to a single hydrophilic polymer. Using Appliant's logic, that would make the hydrophilic polymer a "backbone" as well. Note that the claims do not exclude the presence of more than one backbone in the composition.

Also at page 20, Applicant states that "[a]ccording to the Office Action, as used in the present application, "backbone" is simply an arbitrary term." This allegation is incorrect, as evidenced by the passage from the Action reproduced at the bottom of page 20 in which it is clearly stated that Applicant's arguments are based on an arbitrary definition of the term "backbone". In other words, the Action gives the term "backbone" a reasonable and broad, but not arbitrary definition. In contrast, it would be arbitrary to attempt to limit what is and is not a backbone in the absence of a supporting definition in the specification.

At page 21 of the specification Applicant argues that the Office's interpretation of "backbone" is unreasonable because it is inconsistent with the guidance given in the specification. This is unpersuasive because Applicant fails to point to any definition of "backbone" in the specification that would exclude an interpretation of the hydrophilic polymer of Schacht as a backbone. Applicant depends for support on page 17, line 8 to page 18, line 2. In this passage the word "backbone" is used twice. In the first instance it is used to show where on a PEG molecule propionic acid groups are grafted. Fig. 1 shows that these groups are covalently attached to a carbon in the PEG main chain, i.e. the PEG backbone. Note that the pendant groups are not grafted onto the non-main chain glycol oxygen. This first instance therefore reasonably indicates that the propionic acid groups are directly attached to the main chain or "backbone" of PEG, rather than to non-backbone atoms. As such it provides support for a distinction between what atoms in PEG are part of the backbone, and what atoms in PEG are not. It provides no support for the notion that the Office's interpretation of PEG as a backbone in the invention of Schacht is unreasonable. As a polymer, PEG is considered by those of skill in the art to have a main chain that is also called a backbone. See page 2294 definition 1.34 of the Glossary of Basic Terms in Polymer Science submitted by Applicant in the Response. This has no bearing on which polymer in a carrier comprising several polymers is the "backbone" of the complex. The second instance of "backbone" in this passage states that the carrier is formed from a PEG backbone conjugated to PEI via a linker. Applicant asserts that the passage refers to PEG as "the backbone". This is incorrect. The passage refers to PEG as a "a backbone" and does not serve to exclude from the breadth of the claims an embodiment in which the claimed carrier has more than one molecule that could be referred to as a backbone.

At pages 23 and 24 Applicant argues that the Office's interpretation of "backbone" is unreasonable because it is inconsistent with the guidance given in the specification and is contrary to the plain meaning of the term as under stood by those of skill in the art. Applicant relies for support definition 1.34 on page 2294 of the Glossary of Basic Terms in Polymer Science. This is unpersuasive because the definition concerns the meaning of the term backbone within a polymer, i.e. it is used to distinguish which atoms in a polymer are part of the backbone, and which are pendant. In the instant case, the claimed and prior art carriers comprise different polymeric moieties, each of which has a backbone by virtue of being a polymer. The composition of Schacht allows for multiple attachments of PEG to PEI and of PEI to PEG, and is therefore not really a single polymer. As a result, Applicant's argument that PEI is the backbone of Schacht, is unpersuasive. However, it is noted that the rejections could be overcome by limiting the claims to a carrier molecule consisting of a single PEG polymer to which several pendant PEI molecules are covalently attached. Alternatively, Applicant could amend the claims to make clear that a given molecule of PEI can be attached to only a single molecule of PEG. However, such amendments would require further search and consideration and could be entered only after a Request for Continued Examination.

DAVE TRONG NGUYEN
PRIMARY EXAMINER